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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,003	04/19/2001	Marco Falcioni	10555-022001 / 2000-039	3082

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EXAMINER

ALLEN, MARIANNE P

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 05/12/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,003	FALCIONI ET AL.	
	Examiner	Art Unit	
	Marianne P. Allen	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-100 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-100 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4,5</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claims 56 and 57 are objected to because of the following informalities: These claims lack a period (".") following the number of the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 1-100 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. This is an enablement rejection.

Claims 1-38 are directed to a computer program product on a computer-readable medium for designing a set of experiments. The steps include defining a set of experimental parameters, one or more sampling patterns, and one or more constraints limiting experiments to a particular volume or volumes of a hyperspace, where the experiment design includes a final set of experiments.

Claims 39-68 are directed to a computer-implemented method for designing a set of experiments. The steps include defining a set of experimental parameters, one or more sampling patterns, and one or more constraints limiting experiments to a particular volume or volumes of a hyperspace, where the experiment design includes a final set of experiments.

Claims 69-86 are directed to a computer-implemented method for designing a set of experiments. The steps include defining a set of experimental parameters, selecting one or more

sampling patterns, defining one or more constraints limiting experiments to a particular volume or volumes of a hyperspace, where the experiment design includes a final set of experiments.

Claims 90-93 are directed to a computer-implemented experiment design system comprising means for defining a set of experimental parameters, one or more sampling patterns, and one or more constraints limiting experiments to a particular volume or volumes of a hyperspace, where the experiment design includes a final set of experiments.

Claims 94-99 are directed to a computer program product for designing a set of experiments.

Claim 100 is directed to a computer-implemented method for designing a set of experiments.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation." These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

The specification appears to disclose a computer program product and computer-implemented method where experimental parameters are selected and used to define coordinates in hyperspace. Each point in the hyperspace corresponds to a candidate material. Constraints are chosen to limit the size of the hyperspace or provide a volume or volumes such that a subset of the space is under consideration. From this constrained volume, the space is sampled

according to a particular uniform or non-uniform pattern. This results in some number of candidate materials being identified. If the number is too high (for example), the parameters, sampling pattern and/or constraints may be modified to change the number of candidate materials being identified. When an acceptable number is reached, the library of candidate materials may be produced. The specification appears to indicate that applicant's inventive concept revolves around the efficient search of points in an N-dimensional parameter space rather than by two-dimensional slices or projections through parameter space. (See for example pages 5 and 11.) This is not reflected in the claims.

The specification further discusses that known experiment design techniques may be suited for optimization of processes that are relatively well-understood. They are not well suited for vast parameter spaces, irregular response surfaces, and large libraries. (See for example page 4.) It is noted that the claims are not limited to well-understood chemical processes and encompass vast parameter spaces, irregular response surfaces, and large libraries. The specification does not provide exemplification or guidance on designing sets of experimental parameters for such situations. The specification does not appear to disclose suitable algorithms or implementations. The discussion in the specification is a paper protocol for examples of parameters, sampling patterns, and constraints but fails to provide the underlying mathematical analysis required to practice the claimed invention. The examples in the specification are hypothetical rather than actual experiment designs. The figures are flow diagrams that are essentially black boxes. (See design system 100 and design program 130.) The examples of the specification are also with respect to known chemistry and low-dimensionality. For example, if at least fifty experimental parameters are chosen (see for example claim 29) and each has a

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complex, non-linear sampling pattern, how is the combinatorial expansion calculated? How is the experimental parameter space populated as a volume? How is the first estimate of the practicability determined, particularly where it is not merely a count of candidate materials that is acceptable or unacceptable to a user? There is no evidence of record that implementation of any of these tasks would have been well known or routinely performed by those of ordinary skill in the art at the time of the invention.

For the reasons set forth above, it would constitute undue experimentation to practice the invention as claimed in view of the lack of direction or guidance presented; the absence of working (actual, non-paper) examples; the complex nature of the invention; the acknowledged difficulties in the prior art with respect to high dimensionality experiment design; and the breadth of the claims.

Claim 1-100 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

All of the claims require "designing a set of experiments." However, neither the claims nor the specification make clear exactly what information is to be generated to meet this limitation. It is not known if the output must be a list of compounds to be made or a synthetic scheme to make all of the compounds, perhaps including instructions for the required robotic equipment to execute the synthesis, or some other collection of information. The recitation of "including final set of experiments" implies that there is an intermediate set of experiments

which the claims do not elaborate upon. Use of the term "including" makes the claims indefinite because it does not clearly define what the experiment design is intended to encompass.

Claim 1 recites "one or more sampling patterns defining a sampling for each parameter." It is unclear whether each parameter is associated with one particular sampling pattern or whether one parameter can have multiple sampling patterns at the same time. See also at least claims 39, 69, 90, 94, 96, 98, and 100.

Claim 1 recites "a plurality of the set of parameters being grouped according to a parameter type such that the grouped parameters are constrained to perform a common role in the set of experiments." It is not known from the claims or specification what the metes and bounds of "to perform a common role" are. See also at least claims 39, 69, and 90.

Claim 1 requires generating a first estimate of the practicability, "including a count of the set of experiments." Use of the term "including" makes the claims indefinite because it does not clearly define what information the estimate of practicability is intended to encompass. It is noted that the second estimate of practicability has no recitation of any particular information that must be provided to meet the limitation of the claim. It is not known from the claims or specification what the metes and bounds of "estimate of the practicability" are. See also at least claims 39, 69, 90, and 100.

Claim 1, line 12, recites "the sets of values." This phrase lacks antecedent basis in the claim. It is not known what values are being referred to. It is noted that claim 36 discusses values for properties associated with component materials. However, claim 36 does not appear to require that any use be made of these values or information in the designing the experiments. See also at least claims 39, 66, 69, 87, and 90.

Claim 2 recites "such that the experiment design is capable of being implemented..." It is unclear whether the computer program product is required to have instructions operable to cause this implementation.

Claim 11 recites "parameters of a specified type." It is not known from the claims or specification what the metes and bounds of "specified type" are. For example, if the two parameters are copper (Cu) and fluorine (F), are these the same specified type because they are component materials or are they different specified types because one is a metal and one is a gas? See also at least claims 12, 45, 46, 75, and 76.

Claim 13 is confusing in reciting "limiting the contribution of at least one parameter...based on the contribution of one or more other parameters." As the claims do not specify with particularity what the parameters are, much less their contributions, it is unclear what is intended to be done. The claim does not provide sufficient information as to how or under what circumstances such a limitation would be made. See also at least claims 47 and 77.

Claim 23 recites "selected from the group including balance constraints...or entropy constraints." Use of the term "including" makes the claim indefinite because it does not clearly define what chemistry-specific constraints are intended to be encompassed or excluded.

Claim 38 recites "properties is a type describing a class of chemicals to be used." This is confusing because neither the claims nor specification define what constitutes a class of chemicals or what the different classes may be. See also at least claims 68 and 89.

Conclusion

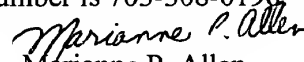
No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne P. Allen whose telephone number is 703-308-0666. The examiner can normally be reached on Monday-Friday, 8:30 am - 2:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 703-308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Marianne P. Allen
Primary Examiner
Art Unit 1631

mpa
May 6, 2003